

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE  
LITIGATION

This document relates to:

*Track One Cases*

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE  
MARKETING CAUSATION OPINIONS OF MARK SCHUMACHER,  
ANNA LEMBKE, AND KATHERINE KEYES**

**TABLE OF CONTENTS**

	<b>Page</b>
I. INTRODUCTION .....	<b>ERROR! BOOKMARK NOT DEFINED.</b>
II. LEGAL ARGUMENT.....	<b>ERROR! BOOKMARK NOT DEFINED.</b>
A. Plaintiffs Fail To Show How Schumacher, Lembke, And Keyes Are Qualified To Give A Causation Opinion About The Impact Of Defendants’ Marketing .....	<b>Error! Bookmark not defined.</b>
B. Plaintiffs’ Sweeping Causation Opinions Are Unreliable For Many Reasons .....	3
1. Plaintiffs Concede That Neither Schumacher, Lembke, Nor Keyes Conducted Any Independent Or Replicable Causation Analyses.....	<b>Error! Bookmark not defined.</b>
2. Plaintiffs Concede Their Experts Failed To Determine That Any Alleged False Marketing Reached Or Influenced Prescribers In Ohio.....	<b>Error! Bookmark not defined.</b>
3. Plaintiffs Make Clear That Schumacher, Lembke, And Keyes Did Not Consider Other Factors On Opioid Prescribing And Abuse.....	5
C. Allowing The Unreliable And Improper Causation Opinions Of Schumacher, Lembke, and Keyes Would Confuse The Jury And Prejudice Defendants .....	6

# **TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>Cases</b>	
<i>In re Aredia &amp; Zometa Prod. Liab. Litig.</i> , 483 F. App'x 182 (6th Cir. 2012) .....	4
<i>In re Diet Drugs (Phentermine Fenfluramine Dexfenfluramine) Prods. Liab. Litig.</i> , No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000) .....	2
<i>In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.</i> , No. 1:08-GD-50000, 2010 WL 1796334 (N.D. Ohio May 4, 2010) .....	2
<i>Johnson v. Manitowoc Boom Trucks, Inc.</i> , 484 F.3d 426 (6th Cir. 2007) .....	5
<i>Nelson v. Tennessee Gas Pipeline Co.</i> , 243 F.3d 244 (6th Cir. 2001) .....	4
<i>Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.</i> , 461 F. Supp. 2d 271 (D.N.J. 2006) .....	2, 3
<i>Pluck v. BP Oil Pipeline Co.</i> , 640 F.3d 671 (6th Cir. 2011) .....	6
<i>Rheinfrank v. Abbott Labs., Inc.</i> , No. 1:13-CV-144, 2015 WL 13022172 (S.D. Ohio Oct. 2, 2015), <i>aff'd</i> , 680 F. App'x 369 (6th Cir. 2017) .....	3

## **I. INTRODUCTION**

Plaintiffs' Opposition ("Opp.") makes clear that the sweeping marketing causation opinions of Schumacher, Lembke, and Keyes rest upon nothing but the mere *assumption* of causal effect. These experts employed no methodology (much less a reliable one) to reach their opinions regarding the alleged causal impact of Defendants' marketing. Nor could they have, as they all lack the necessary marketing experience to give such an opinion. Indeed, Plaintiffs' Opposition concedes that these experts: (a) never conducted any statistical analyses to understand what role, if any, Defendants' marketing played in the rise of opioid prescribing or abuse in the Counties; (b) never spoke to any physicians or patients to identify one prescriber who purportedly was misled; (c) made no meaningful effort to account for the myriad factors that impact prescribing and opioid abuse and mortality; and (d) failed to independently assess the impact of each Defendant's supposedly false marketing. In fact, they apparently reached their speculative causation conclusions *before* this litigation—that is, before having the opportunity to look at any marketing materials by any Defendant in this case. Given their lack of qualifications and any methodology, these experts should be precluded from giving any marketing causation opinion.

## **II. LEGAL ARGUMENT**

### **A. Plaintiffs Fail To Show How Schumacher, Lembke, And Keyes Are Qualified To Give A Causation Opinion About The Impact Of Defendants' Marketing.**

Plaintiffs do not dispute that Schumacher, Lembke, and Keyes have no education, training, or experience in marketing or the regulatory framework that governs pharmaceutical marketing. (Opp. 2-5.) Likewise, Plaintiffs do not dispute that Schumacher and Lembke have no training or experience in conducting statistical analyses—and that Keyes has not conducted one here. (*Id.*) Instead, Plaintiffs summarize various books, reports, and articles published by Schumacher, Lembke, and Keyes and argue they are qualified based on this prior experience alone. But the

materials they reference merely summarize the results of other studies—none of which contain any causation analyses regarding Defendants’ marketing.<sup>1</sup>

For example, Plaintiffs argue that Schumacher’s limited role as one of 18 members on the NASEM committee charged by the FDA with updating the science on pain research and recommending options to address opioid abuse qualifies him to opine on marketing causation. (*Id.* at 2.) However, as Plaintiffs point out, that committee was convened “not to assign blame for the current situation” (*i.e.*, not to determine causation) and merely offered “hypotheses.” (*Id.*) That committee did not undertake an analysis on whether any Defendant’s alleged wrongdoing had any role in the rise of opioid morbidity and mortality. (*See* Ex. 1 to Opp., Dkt. No. 2166-1, at 20-21 (“NASEM Report”) (describing “Statement of Task”).) Nor did the committee examine “Defendants’ marketing”—as Plaintiffs misleadingly suggest. There was no causation modeling or analysis. And most of the Manufacturer Defendants are not even mentioned in the report.<sup>2</sup> Even more fundamentally, Schumacher acknowledged his limited role on NASEM and testified that he did not conduct or review *any* analysis, but merely looked at the results found in the report.<sup>3</sup> That does not render him an expert on marketing causation.

Similarly, Plaintiffs do not dispute that Lembke’s training and experience is limited to the field of addiction medicine—that is, she has no marketing experience. (Opp. 3.) Instead, they

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<sup>1</sup> Plaintiffs rely on *In re Diet Drugs (Phentermine Fenfluramine Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000) and *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08-GD-50000, 2010 WL 1796334 (N.D. Ohio May 4, 2010), but, in those cases, medical experts offered opinions as to a medication or device’s FDA-approved labeling. Here, Plaintiffs’ experts (two of whom are doctors) purport to offer opinions as to the causal impact of marketing—as to which they have no relevant expertise. *See, e.g., Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 461 F. Supp. 2d 271, 276 (D.N.J. 2006) (doctor not qualified to opine on *specific* effects of marketing efforts because he lacked “specialized expertise regarding sales or market analysis” and “conducted no scientific studies or surveys concerning purchasing practices of other doctors in his field”).

<sup>2</sup> The report only references marketing by one company (Purdue), and there is no analysis done to identify any false marketing or link it to any harm. (NASEM Report, at 25-26, 215, 372).

<sup>3</sup> *See* Schumacher April 23, 2019 Dep. Tr., Ex. 9 to Mot., Dkt. No. 1984-11, at 45:21-46:2.

argue that Lembke’s book about opioid addiction qualifies her to give a marketing causation opinion. (*Id.* at 3-4.) Yet Plaintiffs do not argue—much less show—that this book included any type of reliable causal analysis. (*Id.* (arguing only that book addressed “financial support” by unidentified “Defendants” for third-party organizations).) It did not. Notably, even the excerpt provided by Lembke mentions only one manufacturer, and does not cite or review any marketing materials by any Defendant. (Opp. Ex. 2, Dkt. No. 2166-2.) Instead, like her expert report, the book merely summarizes other studies that *do not examine* Defendants’ specific opioid medicines or marketing materials. While Lembke (as an addiction specialist) may be qualified to opine on opioid addiction, her book does not qualify her to opine that Defendants’ marketing caused the opioid abuse “epidemic” in the Counties or anywhere else. *See Pfizer Inc.*, 461 F. Supp. 2d at 276.

Finally, Plaintiffs do not dispute that Keyes has no training or experience with marketing (much less pharmaceutical marketing). (Opp. 4.) Plaintiffs further concede that her published work has nothing to do with marketing; it addresses “substance use disorders” and “opioid-related harm”—not whether marketing was responsible for that harm. (*Id.*) Indeed, the only article Plaintiffs cite to support Keyes’ qualifications is a coauthored one about overdose fatalities. (*Id.*; *see* Opp. Ex. 3, Dkt. No. 2166-3, at 10.) That article offered no marketing analysis, analyzed no marketing, and offered no causation finding. (*Id.*) Notably, Keyes never reviewed any marketing materials in this case. (Keyes April 29, 2019 Dep. Tr., Ex. 7 to Mot., Dkt. No. 1979-10, at 457:8–10.) Her causation opinions should be excluded for lack of qualifications, too. *See, e.g., Rheinfrank v. Abbott Labs., Inc.*, No. 1:13-CV-144, 2015 WL 13022172, at \*11 (S.D. Ohio Oct. 2, 2015), *aff’d*, 680 F. App’x 369 (6th Cir. 2017) (applying principle to exclude testimony).

#### **B. Plaintiffs’ Sweeping Causation Opinions Are Unreliable For Many Reasons.**

In addition to lacking the requisite qualifications, Plaintiffs’ experts simply presume a causal effect—without any real analysis. Indeed, Plaintiffs concede that their experts’ causal

“analysis” rests upon an assumed “correlation” that has to be “more than mere coincidence.” (Opp. 11.) But something “more than mere coincidence” does not create a reliable causation opinion.

**1. Plaintiffs Concede That Neither Schumacher, Lembke, Nor Keyes Conducted Any Independent Or Replicable Causation Analyses.**

Plaintiffs concede these experts conducted no analyses in forming their marketing causation opinions. (*Id.*) Instead, they purportedly “reviewed the evidence and the literature applicable to the Defendants’ promotion of opioid drugs” and then merely “***concluded that the promotion was false and misleading***, and that such false and misleading promotion ***was a cause of the opioid epidemic . . .***” (*Id.* at 6-7 (emphasis added).) But this simply presumes causation—and elides the multiple causal layers along the way. No analysis was done to determine why Ohio prescribers who received marketing from Defendants wrote opioid prescriptions, whether those prescriptions harmed patients, or even whether they led to Plaintiffs’ opioid-related costs. To be admissible, a reliable, replicable analysis must be conducted—an expert may not simply presume a causal effect. *See Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir. 2001) (barring testimony based upon causation assumption). Yet that is precisely what happened here.

Moreover, Plaintiffs do not dispute that the “relevant scientific literature” their experts reviewed consists of general studies of pharmaceutical marketing that do not examine ***these*** manufacturers’ marketing of ***these*** opioid medications or any effect of any alleged false marketing in Ohio. (Opp. 6-10.) Plaintiffs dedicate much of their Opposition to summarizing these articles (most of which are not even cited in their experts’ reports)—which only highlights the lack of a reliable methodology. *See In re Aredia & Zometa Prod. Liab. Litig.*, 483 F. App’x 182, 190 (6th Cir. 2012) (excluding expert’s “specific-causation opinion as unreliable because it was not derived from scientifically valid principles but rather relied exclusively on the scientific literature”).

Worse yet, Plaintiffs' argument that the experts' opinions must be reliable because they formed them *prior* to being retained actually shows the opposite.<sup>4</sup> (Opp. 7.) If Schumacher, Lembke, and Keyes formed their opinions *prior* to being retained, then they did so *without* ever examining the Defendants' marketing materials or other information from discovery to determine whether they were false or misleading and, if so, whether they caused any opioid-related harm in the Counties. Their causation opinions have no reliable foundation and should be excluded.

**2. Plaintiffs Concede Their Experts Failed To Determine That Any Alleged False Marketing Reached Or Influenced Prescribers In Ohio.**

Plaintiffs concede that none of their experts spoke to any Ohio physicians to determine whether they received Defendants' marketing and, if so, to what extent (if any) supposedly false marketing influenced their prescribing. (Opp. 12-13.) Plaintiffs also do not dispute that none of their experts interviewed patients in Ohio to determine how they came to misuse opioids and whether they suffered any harm. (*Id.*) Remarkably, Plaintiffs seem to argue that the causation conclusions of Lembke, Schumacher, and Keyes are reliable merely because pharmaceutical companies market their medicines to physicians in order to increase sales. (*Id.* at 12.) This, once again, merely presumes causation. It says nothing about the impact of any *false* marketing on any Ohio prescribing decision or patient outcome—the very basis for Plaintiffs' claims. Because Plaintiffs' experts conducted no causal analysis, their causation opinions are unreliable.

**3. Plaintiffs Make Clear That Schumacher, Lembke, And Keyes Did Not Consider Other Factors On Opioid Prescribing And Abuse.**

Plaintiffs concede elsewhere that “various actors -- including pill mills, overprescribing doctors, etc. -- were responsible for at least a portion of the opioid crisis.”<sup>5</sup> Yet Plaintiffs do not

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<sup>4</sup> Plaintiffs cite *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426 (6th Cir. 2007), but the Sixth Circuit affirmed the exclusion of expert testimony there. *Id.* at 435. Similarly, here, the experts conducted no causation analysis of Defendants' marketing—either before or after retention.

<sup>5</sup> See Pls.' Mem. in Opp. to Defs.' SOL Mot. for Partial Summ. J., Dkt. No. 2179, at 6 n.23.



dispute that Schumacher, Keyes, and Lembke did not conduct a meaningful analysis of these or the many other independent factors leading to opioid-related harm in forming their causation opinions. (Opp. 14.) At most, Plaintiffs' Opposition merely points to a single cursory and generalized statement or two in their expert reports (or depositions) about "others" having "some responsibility for the events that have transpired." (*Id.* (quoting Lembke's report).) But Plaintiffs fail to show *how* their experts accounted in any reliable way for the role other factors played in the increase in opioid prescribing and abuse in Ohio, including what data they reviewed or how they assessed it. Merely assuming causation without ruling out alternative causes is not sufficient for an expert opinion. *See Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 680 (6th Cir. 2011) (excluding expert opinion for failing to "'rule out' alternative causes").

Plaintiffs also concede that Schumacher, Lembke, and Keyes did "not consider each defendant separately in order to offer opinions," much less measure the impact of each Defendant's alleged false marketing. (Opp. 15.) Instead, they argue that the marketing causation opinions need "not be sufficient" on their own to establish causation to be admissible, yet fail to address how lumping all of the Defendants together would assist the trier of fact to determine whether each Defendant's marketing (much less false marketing) caused a rise in opioid misuse. (*Id.* at 15-16.) This is particularly so given that Plaintiffs recognize that they must "prove their claims against *each individual defendant* based on each defendant's alleged wrongdoing." (Pls.' Mot. To Sever, Dkt. No. 2099, at 2 (emphasis added).) The aggregate causation opinions of Schumacher, Lembke, and Keyes will not assist the trier of fact in resolving claims against "each individual defendant."

**C. Allowing The Unreliable And Improper Causation Opinions Of Schumacher, Lembke, and Keyes Would Confuse The Jury And Prejudice Defendants.**

Schumacher, Lembke, and Keyes are not economists trained to perform a data-driven analysis to establish causation. They have no experience with pharmaceutical marketing. They

have never conducted any independent analyses as to the impact of Defendants' marketing, much less in Ohio. They also did not evaluate or account for any other factors that could have led to a rise in opioid morbidity and mortality. As a result, it would be prejudicial to allow such speculative and untested causation opinions. Plaintiffs also have other experts through which they seek to provide causation testimony. (Opp. 16.) Because the duplicative and unreliable causation testimony of Schumacher, Lembke, and Keyes will only mislead the jury, it should not be admitted.

Dated: August 16, 2019

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<sup>6</sup> Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion as a result of the Court's deadline to file dispositive and Daubert motions, and, thus, they do not waive and expressly preserve their pending personal jurisdiction challenges.

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on August 16, 2019, Defendants' Reply In Support of Their Motion To Exclude The Marketing Causation Opinions Of Mark Schumacher, Anna Lembke, And Katherine Keyes was served via email on all attorneys of record consistent with the June 24, 2019 Order setting forth Directions Regarding Filing of Briefs Under Seal.

/s/ Steven A. Reed  
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